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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,749	08/27/2003	Kim R. Harmon	ZIM0402	7336
7590 John F. Hoffman, Esq. BAKER & DANIELS LLP Suite 800 111 East Wayne Street Fort Wayne, IN 46802			04/19/2007 EXAMINER SOLANKI, PARIKHA	
			ART UNIT 3737	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/19/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/649,749	Applicant(s) HARMON ET AL.	
	Examiner Parikha Solanki	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-20 is/are pending in the application.
- 4a) Of the above claim(s) 14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-13 and 16-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8/27/03 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/8/07</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Response to Arguments***

1. Applicant's arguments filed 9 January 2007 have been fully considered but they are not persuasive.

Applicant argues that Marmulla (US PG Pubs. No. 2002/0183608) fails to disclose or suggest "a set of tracking arrays including a first array body having a first array of tracking elements in a predetermined spatial configuration and a second array body having a second array of tracking elements in a predetermined spatial configuration distinct from the predetermined spatial configuration of the first array of tracking elements" (Remarks 1/9/07, p. 8). Examiner maintains that Marmulla ('608) does in fact disclose the claimed invention; specifically, Marmulla ('608) states that the apparatus "can also be in the form of a base on which a 3-D marker is placed ... [and] can also be formed directly by one or several 3-D markers, which constitutes the claimed first array of tracking elements in a predetermined spatial configuration (§ 0025). Marmulla ('608) goes on to disclose "[a]dditional 3-D markers 8 which are either attached directly on a bone segment 9 or on a work tool 15" (§ 0030), constituting the claimed second array of tracking elements in a predetermined configuration different from the first configuration. Marmulla ('608) also states that an additional set of markers may be attached to the marker position detection unit (0032), which would alternatively constitute a second array as claimed in the instant application.

Applicant additionally argues that Marmulla ('608) does not disclose or suggest "a multiple configuration tracking array including an array body and a predetermined number of tracking elements positionable in alternate configurations to produce alternate patterns". Examiner respectfully directs Applicant's attention to Figure 3 of Marmulla ('608), which shows that either LED or reflective tracking elements may be disposed in variable spatial configurations on the base plate. This constitutes a multiple-configuration tracking array as claimed in the instant application.

Applicant also contends that Marmulla ('608) lacks "a surgical navigation system including means for tracking an object by detecting the positions of a predetermined number of tracking elements, and an array body having a predetermined number of tracking element attachment locations, the tracking elements being positionable in alternate configurations of attachment locations." Applicant also states that Marmulla ('608) does not disclose or teach "a surgical navigation system including an array and a plurality of tracking elements, the position of at least one element being adjustable to produce alternate spatial arrays of tracking elements." As set forth above, Examiner maintains that Marmulla ('608) does in

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fact disclose the array and tracking elements of the instant application. Examiner further clarifies that the scanner and marker position detection unit (§ 0032) disclosed by Marmulla ('608) constitute means for tracking an object as claimed in the instant application.

Examiner maintains the rejections set forth in the previous Office Action, the details of which are reiterated below with minor modifications made to address Applicant's claim amendments.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claim 16 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 6 of copending Application No. 11/039,040. Although the conflicting claims are not identical, they are not patentably distinct from each other because they all describe a surgical navigation array having a body and a plurality of tracking elements mounted to the body, the position of at least one element being adjustable to produce alternate spatial arrays of tracking elements. Claims 17-20 of the instant application are also rejected on the ground of nonstatutory obviousness-type double patenting in view of their dependence on claim 16.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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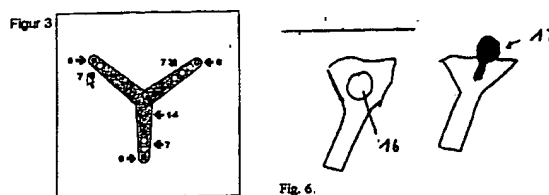
4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 4-13 and 16-20 are rejected under 35 U.S.C. 102(a) as being anticipated by Marmulla (US PG Pub. No. 2002/0183608), previously made of record by Applicant, further supported by Marmulla (US Patent No. 7,079,885).

Regarding claims 4-6, 13 and 16-20, Marmulla ('608) discloses a surgical navigation marker, equivalent to an array, having a body and a plurality of tracking elements adjustably attached to the body, for use with a surgical navigation system that includes means for detecting the position of the elements (Figs. 3 & 6, ¶ 0022). Marmulla ('608) also discloses that at least three arrays may be attached to the patient during surgery (¶ 0025). Marmulla ('608) further discloses that the spatial characteristics of the array may be used to uniquely identify the position of the array (¶ 0033). The array of Marmulla ('608) has a plurality of tracking element attachment locations, which may outnumber the tracking elements attached to the array (Fig. 3). The number of tracking elements of Marmulla ('608) may also be chosen so as to ensure that the array to which the elements are attached is still uniquely identifiable in the event that one of the tracking elements is blocked from detection (Fig. 3). Marmulla ('608) discloses that the tracking elements may comprise planar reflective surfaces (¶ 0022). The array of Marmulla ('608) is additionally capable of receiving tracking elements in alternate configurations of attachment locations; for example, Marmulla ('608) shows that the array is capable of receiving either LED or reflective markers, and it would therefore be possible for one to modify the number and/or position of either or both types of markers.



(Source: Marmulla et al, US PG Pub. No. 2002/0183608)

Regarding claim 7, Marmulla ('608) does not discuss how the array body is molded. However, the recitation “the array body is molded from a polymer” is a product by process limitation. If the product in a product by process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. Therefore, one of

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reasonable skill in the art would consider the array of claim 7 to be the same as the array disclosed by Marmulla ('608) even though the two inventions might be molded differently. See MPEP § 2113 for further discussion regarding patentability of product by process claims.

Regarding claim 8, Marmulla ('608) shows that the array body may include a cylindrical recess at the attachment locations, engageable with cylindrical members of the tracking elements (Fig. 3). For additional clarification, Applicant may also wish to reference the corrected Figure 6 provided in Marmulla ('885), which better illustrates the basis of Examiner's rejection. Marmulla ('608) shows that the portion of the marker engaged with the array is itself of cylindrical shape, and therefore it follows that the point at which the two elements are coupled constitutes a cylindrical recess.

Regarding claims 9-12, Marmulla ('608) discloses that the tracking elements may be LEDs, reflectors, ultrasound transmitters, or electromagnetic transmitters (§ 0022).

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Rossner (US PG Pub. No. 2003/0225329), Heilbrun (US PG Pubs. No. 2001/0039421) and Barnett (US Pat. No. 5,904,691) disclose related tracking devices with adjustable markers for use with a surgical navigation system.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parikha Solanki whose telephone number is 571.272.3248. The examiner can normally be reached on M-F, 8 - 4:30pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571.272.4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Parikha Solanki
Examiner - Art Unit 3737


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